

PATENT

Application No. 10/563,566  
Docket Nos. 187287/IJS*In the Claims:*

This listing of claims will replace all prior versions, and listings, of claims in the application.

1-22. (Cancelled)

23. (New) A formulation for a controlled drug or drug of abuse presented in a format such that:

- (a) a patient's access to the formulation is controlled; and
- (b) the patient's access to the formulation is monitored in real time;

such that the control over the patient's usage of the formulation does not require the supervision of a healthcare professional at the time of administration.

24. (New) The formulation as claimed in claim 23, wherein the controlled drug or drug of abuse is a class A drug in a non-intravenous formulation, as defined by The Misuse of Drugs Act 1971.

25. (New) The formulation as claimed in claim 23, wherein the controlled drug or drug of abuse is an opioid.

26. (New) The formulation as claimed in claim 25, wherein the opioid is methadone or a pharmaceutically acceptable salt or derivation thereof.

27. (New) The formulation as claimed in claim 26, wherein the opioid is methadone hydrochloride.

28. (New) The formulation as claimed in claim 26, wherein the opioid is for oral delivery.

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29. (New) The formulation as claimed in claim 25, wherein the opioid is diamorphine or a pharmaceutically acceptable salt or derivative thereof.
30. (New) The formulation as claimed in claim 29, wherein the opioid is diamorphine hydrochloride.
31. (New) The formulation as claimed in claim 29, wherein the diamorphine is dry and suitable for nasal delivery upon mixing with an aqueous solution.
32. (New) The formulation as claimed in claim 31, wherein the formulation for nasal delivery further comprises a solubility enhancer.
33. (New) The formulation as claimed in claim 32, wherein the solubility enhancer is one or more of caffeine, sodium benzoate and sodium salicylate.
34. (New) The formulation as claimed in claim 32, wherein the solubility enhancer comprises caffeine, sodium benzoate, sodium salicylate, or a combination thereof.
35. (New) The formulation as claimed in claim 31, wherein the formulation for nasal delivery is a freeze-dried formulation.
36. (New) The formulation as claimed in claim 23, wherein a number of doses of the formulation are supplied to the patient.

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***In the Drawings:***

The attached sheet of drawings includes changes to FIGS. 4 and 5, namely the removal of reference numerals 23, 24 and 28. This sheet, which includes FIGS. 4 and 5, replaces the original sheet including FIGS. 4 and 5.

Attachment: Replacement Sheet 4/7 including FIGS. 4 and 5.